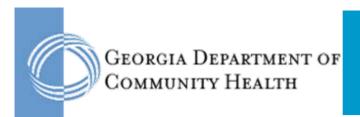


Introduction to Certificate of Need

Health Strategies Council February 17, 2006



Agenda

- What is Certificate of Need ("CON")
- Goals of CON
- Health Care Services that Require a CON
- How to Obtain a CON
- How is a CON Application Reviewed
- CON Exemptions
- Sanctions



What is CON

- Certificate of Need is the official determination that a new or expanded health care service or facility is needed in Georgia
- CON is one component of the State's overall health planning function established by Chapter 6 of Title 31 of the State Code
 - In Georgia, this health planning process has been in place since 1979



Goals of CON

- To ensure that adequate health care services and facilities are:
 - Available to the citizens of the State;
 - Developed in an orderly and economical manner; and
 - Provided in a manner that avoids unnecessary duplication
- To ensure that only health care services that are found to be in the public interest are offered
- To ensure that health care services meet the various needs of the different regions of the State

O.C.G.A. § 31-6-1



Health Care Services that Require a CON

- Construction or development of a new health care facility
- Any expenditure by or on behalf of a health care facility in excess of \$1.395 M
- Any increase in bed capacity of a health care facility
- Clinical health services which are not offered on a regular basis in or through a health care facility within the previous 12 months
- The purchase, lease, or use of diagnostic or therapeutic equipment with a value in excess of \$775 K
- Radiation Therapy, Ambulatory Surgery, Biliary Lithotripsy, and Cardiac Cath offered in freestanding facilities

O.C.G.A. § 31-6-2(14)



Services that Require a CON: Clinical Health Services

Acute Care Related Services

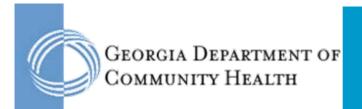
- Short Stay Hospital Beds
- Adult Cardiac Catheterization
- Open Heart Surgery
- Pediatric Cardiac
 Catheterization and Open
 Heart Surgery
- Perinatal Services
- Freestanding Birthing Centers
- Psychiatric and Substance Abuse

Special and Other Health Services

- Ambulatory Surgery Centers
- Positron Emission Tomography
- Radiation Therapy Services
- Magnetic Resonance Imaging
- Computed Tomography

Long Term Care Services

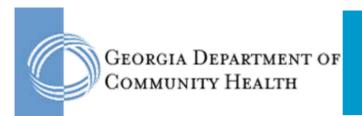
- Skilled Nursing
- Personal Care Home
- Continuing Care Retirement
 Communities
- Traumatic Brain Injury Facilities
- Comprehensive Inpatient Physical Rehabilitation
- Long Term Care Hospitals



How to obtain a CON

CON Application

- Submitting an Application and Paying Filing Fees
 - The amount of a filing fee is determined by the cost of a proposed project according to the following schedule:
 - a) \$1,000 is the minimum filing fee and covers projects costing zero to \$1,000,000;
 - b) one-tenth of one percent (0.001) for projects costing more than \$1,000,000 with **no filing fee exceeding \$50,000**
- An application must be determined complete before substantive review of the application begins
- The review period is 90 days and may be extended an additional 30 days, if necessary. In no event shall a review exceed 120 days.



How to obtain a CON

What Happens at the End of the Review Period?

A project application, if not withdrawn, is either approved or denied by the Office of General Counsel. If the application is approved, an official Certificate of Need and project evaluation analysis is provided to the applicant. If the project is denied a denial letter and project evaluation analysis is provided to the applicant.



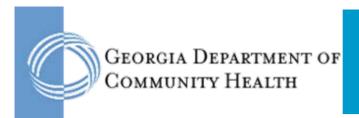
How is a CON Application Reviewed: General Considerations

- The population residing in the health planning region has a need for services
- Existing alternatives to the proposed service are currently unavailable
- The proposed service is financially feasible
- The effects on health care payors are reasonable
- The construction costs are reasonable and adequate
- The service will be financially and physically accessible
- The proposed service will have a positive relationship to the existing health care delivery system

O.C.G.A. § 31-6-42



- Each clinical health service has a service specific rule which expounds upon the general considerations
- These service specific considerations must be addressed and satisfied in addition to the general considerations



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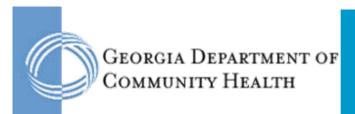


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Adult Cardiac Catheterization: Need

Defined Health Planning Areas

Population-Based Need Methodology

< [{[(State Adult Caths \div State Adult Population)

 χ

Projected Planning Area Population]

 χ

(1 + % of out-of-state caths performed in Planning Area)}

 χ

State-Wide Rate of Equivalents

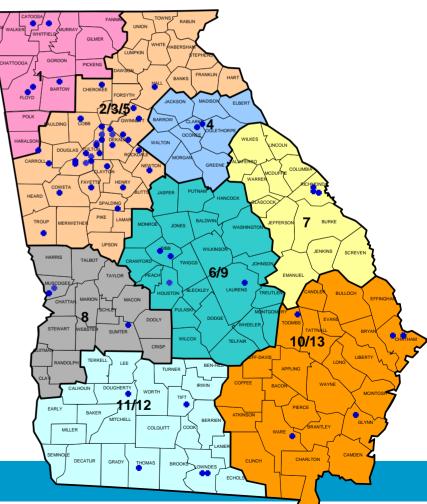
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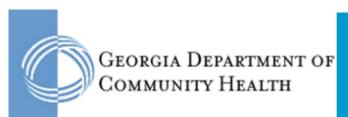
(Existing Inventory of Cath Labs x 1300)>

=

Number of Cath Labs Needed

Exceptions to Need





Adult Cardiac Catheterization: Existing Alternatives

 Aggregate Utilization in Planning Area must equal 85% before additional services can be added

Adult Cardiac Catheterization: Financial Feasibility

- Document that at least 1,040 annual procedures will be performed within the first three years of operation
- Must have a cardiologist recruiting plan





Adult Cardiac Catheterization: Effects on Payors

 Proposed charges must be reasonable and comparable to other providers

Adult Cardiac Catheterization: Construction Costs

 Must propose a plan to meet minimum physical facility requirements of the American College of Cardiology



Adult Cardiac Catheterization: Financial Accessibility

- Applicant must commit to provide at least 3% AGR in indigent and charity care services
- Applicant must provide policies relating to nondiscriminatory treatment of patients



Adult Cardiac Catheterization: *Positive Relationship with Delivery System*

- Proposed service cannot result in the existing service providers' service volumes to decrease to less than 80% of capacity
- Must submit policies relating to continuity of care
- Must become JCAHO accredited



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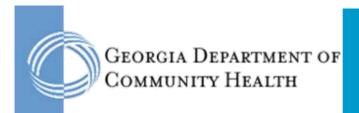
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O.C.G.A. § 31-6-2(14)



CON Exemptions

- Physician Owned, Single Specialty, Office Based Ambulatory Surgery Centers established at a cost less than \$1.515 M
- Equipment acquired at a cost of less than \$775 K
- Replacement of CON-authorized equipment
- University Infirmaries
- Federal Health Care Facilities
- Business Infirmaries
- Offices of Private Physicians
- Acquisitions of existing CON-authorized facilities
- Expenditures to eliminate safety hazards or to comply with accreditation standards
- 10 percent increase in bed capacity if utilization has exceeded 85 percent for the previous 12 month period



- 1. Operating room environment
- 2. Performed in the offices
- 3. Individual private physician or single group practice of private physicians
- 4. Owned, operated, and utilized by such physicians
- 5. Of a single specialty
- 6. Does not exceed the amount of \$1.515 M

Source: OCGA § 31-6-2(14)(G)(iii)





Requirement: Operating Room Environment

 OCGA 31-6-2(16.1) and Department's regulations define "operating room environment"

 Minimum physical plant standards of DHR

Source: Ga. Comp. R. & Regs. r. 272-2-.07(4)(g), (h), (j)



Requirement: Office-Based

- Reasonable proximity to a clinical office space
 - Interpreted to mean in the same building as office space



Source: Ga. Comp. R. & Regs. R. & Regs. r. 272-2-.07(4)(f)



Requirement: Individual Physician or Group Practice

- Evidence of Sole Physician Corporation or Group Practice, e.g. articles of incorporation, by-laws, operating agreements
- Affidavit stating that each physician belongs only to one practice

Source: Ga. Comp. R. & Regs. R. & Regs. r. 272-2-.07(4)(d), (l) - (



Requirement: Physician-Owned

- Must have at least 85% licensed physician ownership
- Ownership evidence must be submitted, e.g. stock certificates, operating agreement
- Must submit site entitlement documentation

Source: Ga. Comp. R. & Regs. r. 272-2-.07(4)(b)-(e)





Requirement: Single Specialty

- All members and employed physicians must be of same surgical specialty
- Evidence generally includes an affidavit or documentation of specialty listed with Composite Medical Board



Source: Ga. Comp. R. & Regs. r. 272-2-.07(4)(b)



Requirement: Single Specialty

- Neither Statute nor Regulations define "single specialty"
- Regulations define "multi-specialty"
 - Any ASC offering general surgery or any combination of general surgery and any number of the following specialties:
 - Dentistry/oral surgery
 - Gastroenterology
 - OB/GYN
 - Ophthalmology
 - Podiatry
 - Pulmonary Medicine

- Orthopedics
- Otolaryngology
- Pain Management/ Anesthesiology
- Plastic Surgery
- Urology

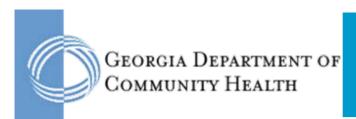
Source: Ga. Comp. R. & Regs. r. 111-2-2-.40(2)(j)



Requirement: Does not Exceed \$1.515 M

- Amount is adjusted annually for inflation in construction indices
- Includes all capital expenditures made by or on behalf of the physician or group in establishing and developing the ASC for the first three years including:
 - Construction
 - Equipment
 - Legal, consulting, and administrative fees
 - Interest during construction
 - Furnishings

Source: Ga. Comp. R. & Regs. r. 272-2-.07(4)(i), (k), (p), (q)



CON Exemptions:Diagnostic or Therapeutic Equipment

- Equipment that can be acquired for less than \$775 K is exempt
- The dollar threshold includes associated costs such as construction, functionally related equipment, furnishings



Differences between CON and LNR Processes





- No Need Analysis
- No Commitment to Indigent and Charity Care
- Limited to Statutory Restrictions
- No Review of Quality
- No Review of Fees
- No Requirement to Report Statistical Data

- Calculated Need Must Exist
- Must Commit to Provide 3% of annual AGR to Indigent and Charity Care
- No limitations on ownership, location, cost, specialty, etc.
- Minimum quality standards must be met
- Fees must be Reasonable
- Must Report Annual Data



Sanctions

What are the Sanctions for Failing to Comply with CON laws?

 DCH may issue cease and desist mandates and/or seek court injunctions to halt violations as well as impose maximum fines of \$5,000 per day for every day a violation to the CON rules and regulations exists.



Questions

